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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/814,251	03/21/2001	Robert W. Stadler	P-8777	5575

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EXAMINER

OROPEZA, FRANCES P

ART UNIT PAPER NUMBER

3762

DATE MAILED: 06/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/814,251

Applicant(s)

STADLER ET AL.

Examiner

Frances P. Oropeza

Art Unit

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 9/25/03 (Amendment and RCE).
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4,5 and 7-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4,5 and 7-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Petition to Revive

1. The Applicant's petition to revive the instant application was granted 12/15/03.

Request for Continued Examination

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. The Applicant's submission filed on 9/25/03 has been entered.

Response to Amendment

3. The claims of record were successfully amended to overcome the art of record, hence a new grounds of rejection is established for the pending claims.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 4 and 5 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant

art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Specifically claim 1 recites “the threshold number is set as a value which increases as an inverse function of the length of the intervals between depolarizations”.

Specifically claim 4 recites “the threshold number is set as a value which increases as an inverse function of a defined percentile of the length of the intervals over a sequence of a predetermined number of intervals between depolarizations”.

Specifically claim 5 recites “the threshold number is set as a value which increases as an inverse function of the 75th percentile of the length of the intervals over a sequence of a predetermined number of intervals between depolarizations”.

The original application discusses the threshold number on page 4, lines 23-31 and in claims 4 and 5 on page 24 of the instant specification. The Examiner is unable to find support for the currently claimed limitations in the specification. New matter may not be entered at this point in the prosecution. Appropriate correction is required.

Claim Rejections - 35 USC § 102

5. Claims 1, 4 and 7-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Gunderson (US 5330508). Gunderson discloses an apparatus to sense depolarizations, measure depolarization intervals, store the intervals, detect tachyarrhythmia, and discriminate between the tachycardia and fibrillation using sorting of intervals into bins, counting the number of intervals per bin, defining the threshold criteria point and triggering therapy if the criteria point is met (Abstract; col. 2 @ 63 – col. 3 @ 25).

As to claims 1, 4 and 5, the threshold number is read as a predetermined number of bins that exceed a ratio (percentage) of intervals attaining at least a predetermined threshold. The threshold number is accepted to increase as an inverse function of the length of the interval (col. 2 @ 67 – col. 3 @ 7; col. 4 @ 3-9, 19-27). As to claim 1 and the threshold number being set as a value which increases as an inverse function of the length of the intervals between depolarizations, Gunderson teaches an embodiment where the length of the intervals are monitored and as the intervals become shorter, moving from high rate tachycardia to fibrillation, the threshold value increases (col. 2 @ 63 - col. 3 @ 9). As to claim 4 and the threshold number increasing as an inverse function of a defined percentile of the length of the intervals, Gunderson teaches an embodiment where the length of the intervals are monitored and as the intervals become shorter, moving from high rate tachycardia to fibrillation, the threshold value increases. The ratio of intervals is read as a percentage (col. 2 @ 63 - col. 3 @ 9).

As to claims 1, 4 and 5 and a means for defining a discrimination criteria based on the bins and the interval in them, the means for defining the discrimination criteria is the establishment of preset parameters in the device during manufacture, or allowing the physician to program the parameters during implantation (col. 4 @ 10-27), and the parameters are the bins and the intervals in them (col. 2 @ 63 – col. 3 @ 7). The threshold values and parameters are varied/ adjusted depending on the arrhythmia detected (col. 12 @ 40-56).

As to claim 7, the apparatus distinguishes between VT and VF and provides appropriate therapy (col. 3 @ 6-16).

As to claim 8, the apparatus distinguishes between VT and AF and provides appropriate therapy (col. 3 @ 17-25).

As to claim 9, the threshold number is variable based on the detected arrhythmia (col. 4 @ 19-22; col. 10 @ 62 – col. 11 @ 8; col. 12 @ 9-21).

Claim Rejections - 35 USC § 103

6. It appears figures 8 a-c were not included in the application as originally filed. Figure 8a is described in the specification as a scatter plot apparently related to claim 10. The Applicant indicated in his 9/25/03 response that a complete set of drawings were attached, but the Examiner finds no such drawings, hence the following rejection reflects the Examiner's best understanding of claims 10 and 11.

Claims 5, 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gunderson (US 5330508) in view of Rossing (US 5464430). As discussed in paragraph 3 of this action, Gunderson discloses the claimed invention except for: 1) the threshold value increasing as a function of the 75th percentile of the length of the intervals of a predetermined number of intervals (claim 5), and 2) the threshold value decreasing as a function of the 75th percentile of the length of the intervals of a preceding series of depolarizations (claims 10 and 11).

Rossing teaches arrhythmia discrimination:

1) using a threshold number varying as an increasing or decreasing function of the cycle lengths (intervals) for the purpose of defining different arrhythmias, and

2) using the 75th percentile cycle length of a preceding sequence of depolarizations as the measurement metric for the purpose of providing a stringent criteria to judge cardiac rhythms and define specific arrhythmias.

It would have been obvious to one having ordinary skill in the art at the time of the invention to have used the threshold number varying as an increasing or decreasing function of the cycle length and to have used the 75th percentile cycle length as the measurement metric in the Gunderson system in order to distinguish between the various tachyarrhythmias so appropriate therapy can be provided to the patient (col. 1 @ 10-15; col. 2 @ 34-63; col. 4 @ 3-17).

As to claim 5 and the threshold number being a set value which increase as an inverse function of the 75th percentile of the length of the intervals, Gunderson teach an embodiment where the length of the intervals are monitored and as the intervals become shorter, moving from high rate tachycardia to fibrillation, the threshold value increases (col. 2 @ 63 - col. 3 @ 9). The Rossing reference is combined with Gunderson for the teaching that the 75th percentile cycle length is a stringent criteria appropriately used to judge cardiac rhythms (col. 4 @ 7-13).

Specification

7. The amendment filed 9/25/03 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows:

Claim 1 recites "the threshold number is set as a value which increases as an inverse function of the length of the intervals between depolarizations".

Claim 4 recites "the threshold number is set as a value which increases as an inverse function of a defined percentile of the length of the intervals over a sequence of a predetermined number of intervals between depolarizations".

Claim 5 recites "the threshold number is set as a value which increases as an inverse function of the 75th percentile of the length of the intervals over a sequence of a predetermined number of intervals between depolarizations".

Applicant is required to cancel the new matter in the reply to this Office Action.

Drawings

8. Figures 6, 7, and 8 a-c are referenced in the specification, but these figures were apparently not included in the application as originally filed. These figures should be submitted for potential inclusion in the application, assuming no new matter is presented, or reference to these figures should be deleted from the specification. The Applicant indicated in his 9/25/03 response that a complete set of drawings were attached, but the Examiner finds no such drawings

Statutory Basis

9. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Conclusion

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Fran Oropeza, telephone number is (703) 605-4355. The Examiner can normally be reached on Monday – Friday from 9 a.m. to 5 p.m.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Angela D. Sykes can be reached on (703) 308-5181. The fax phone number for the

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organization where this application or proceeding is assigned is (703) 872-9306 for regular communication and for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Receptionist, telephone number is (703) 308-0858.

Frances P. Oropeza
Patent Examiner
Art Unit 3762

FPO
5/23/04

Angela D. Sykes

ANGELA D. SYKES
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